

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
26 May 2005 (26.05.2005)

PCT

(10) International Publication Number
WO 2005/046782 A1

(51) International Patent Classification⁷: **A61M 27/00, A61F 9/007**

(74) Agents: ROBERTS, Mark et al.; Davies Collison Cave, Level 10, 10 Barrack Street, Sydney, New South Wales 2000 (AU).

(21) International Application Number:
PCT/AU2004/001566

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date:
12 November 2004 (12.11.2004)

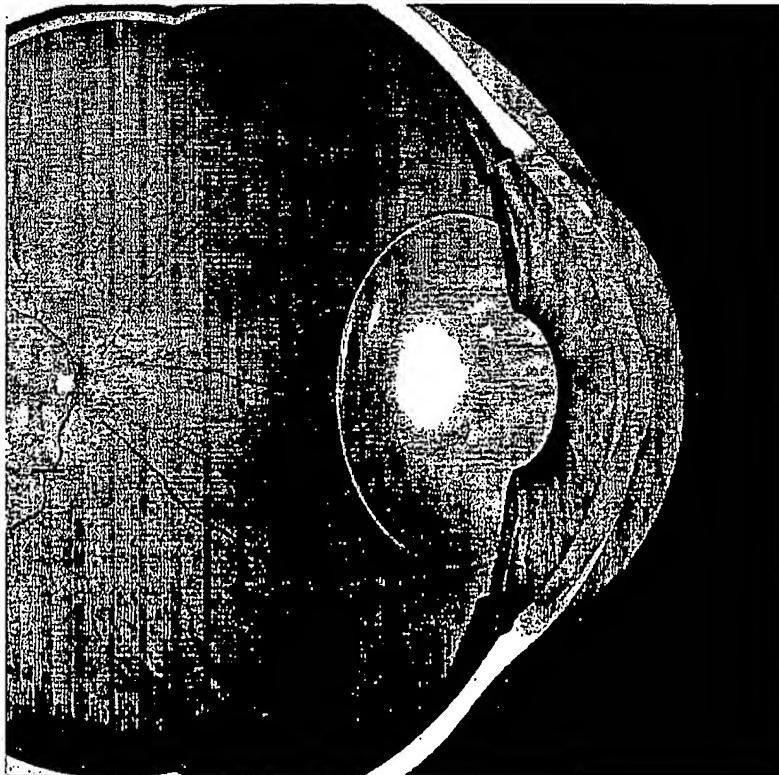
(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

(25) Filing Language: English
(26) Publication Language: English
(30) Priority Data:
10/712,277 14 November 2003 (14.11.2003) US

(71) Applicant and
(72) Inventor: CORONEO, Minas, Theodore [AU/AU]; 44 Olola Avenue, Vaucluse, New South Wales 2030 (AU).

[Continued on next page]

(54) Title: OCULAR PRESSURE REGULATION



(57) Abstract: This invention comprises a flexible ocular device for implantation into the eye formed of a biocompatible elastomeric material, foldable to a diameter of 1.5 mm or less, comprising a fluid drainage tube having at one end a foldable plate adapted to locate the device on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis, said drainage tube opening onto the disc at one end and opening to the anterior chamber when implanted into the eye at its other end, so as to provide aqueous pressure regulation. Also provided are methods for the treatment of glaucoma utilising the flexible ocular device, and an ocular pressure spike shunt.

WO 2005/046782 A1



FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

OCULAR PRESSURE REGULATION

Field of the Invention

This invention is directed to therapeutic methods and devices for the treatment of glaucoma. In particular, this invention is concerned with the use of a shunt or drain for the treatment of glaucoma. In another aspect this invention is concerned with ocular pressure spikes shunts and use of the same in ocular surgery.

Background of the Invention

10 The glaucomas are a common group of blinding conditions usually associated with elevated intraocular pressure. This elevated pressure in the eye may be regarded as a disorder of the drainage system of the eye which gives rise to the glaucomas.

15 Aqueous humor of the eye ("aqueous") is a flowing liquid fluid (composed of sodium, chloride, bicarb, amino acids, glucose, ascorbic acid, and water) that is actively secreted by the ciliary body and flows out past the iris into the anterior chamber (are between the lens/iris and the cornea). The aqueous drains out through angle formed by the iris and the sclera into a meshwork call the trabeculum, and from there into the canal of Schlem and then into the episcleral veins. Uveosclera drainage also occurs. Normal intraocular 20 pressure (IOP) of aqueous in anterior chamber is between 10 and 20 mm Hg. Prolonged IOPs of greater than 21 mm Hg are associated with damage to optic nerve fibres.

In some cases of glaucoma the cause can be found: the trabecular meshwork becomes blocked by pigment or membrane. In other cases, blockage is due to a closure of the angle 25 between the iris and the cornea. This angle type of glaucoma is referred to as "angle-closure glaucoma". In the majority of glaucoma cases, however, called "open angle glaucoma", the cause is unknown.

30 Elevated intraocular pressure results in the death of retinal ganglion cells (which convey retinal information to the brain) resulting in a characteristic pattern of loss of the field of vision, progressing to tunnel vision and blindness if left untreated.

- 2 -

Treatment of glaucoma consists predominantly of methods to lower the intraocular pressure (pharmacological, trabecular meshwork laser and surgery to drain fluid from the eye). More recently protection of the retinal ganglion cells by neuroprotective agents has
5 been attempted.

Although pharmacological treatments of glaucoma have improved, they have important implications for the patient's quality of life, have compliance issues which are important in the elderly (in whom glaucoma is prevalent), expose the patient of glaucoma to side
10 effects, and over a lifetime are costly.

Surgery for glaucoma treatment is usually a trabeculectomy in which a fistula is created to drain fluid from the anterior chamber to the subconjunctival space near the limbus, creating a bulge in the conjunctiva known as a bleb. Frequently scarring occurs and
15 attempts to counter this with antimetabolites such as Mitomycin C have met with some success. In recalcitrant cases, glaucoma implants, drainage, shunt or valve devices have been developed eg Molteno (US Patent 4,457,757), Krupin (US Patent 5,454,746) and Baerveldt (US Patent 5,178,604). These suffer from similar problems of scarring (Classen L, Kivela T, Tarkkanen "A Histopathologic and immunohistochemical analysis of the
20 filtration bleb after unsuccessful glaucoma seton implantation" *Am J Ophthalmol*, 1996;122:205-12) around the external opening of the tube devices in the subconjunctival space – the development of a large number of these devices is testament to the fact that many fail in the longer term. In these devices a drainage tube is located in the anterior chamber and is in fluid communication with the sclera or a surgically created
25 subconjunctival space.

Whereas cataract surgery has been revolutionized in the last two decades, improvements in glaucoma surgery have been slower. Antifibrotic agents have improved the success rate of conventional filtration surgery (trabeculectomy), but with increased bleb leaks, blebitis,
30 endophthalmitis and hypotensive maculopathy. Glaucoma shunts have had limited success in eyes that have "failed" multiple standard procedures. However complications with

malpositioned tubes, erosion & strabismus persist. A considerable issue is the lack of reproducibility and predictability in achieving the desired target intraocular pressure (IOP). Final IOP is largely determined by healing which can be unpredictable – in view of vast biological variations, it is impossible to predict which eyes will rapidly scar causing failure 5 and which will fail to heal resulting in prolonged post-operative hypotony. Scarring remains a significant problem in all these external drainage proposals, where aqueous drains into the conjunctiva, or surgical chambers in the sclera.

The introduction of a new class of antiglaucoma drugs, the prostaglandin analogues has 10 resulted in acknowledgment of the importance of the uveoscleral pathway in drainage of fluid from the eye (Hylton C, Robin AL "Update on prostaglandin analogs" *Curr Opin Ophthalmol*, 2003;14:65-9). Uveoscleral flow where aqueous humor flows through the interstitium of the ciliary muscle into the suprachoroidal space (a potential space between the choroids and sclera) and out through the sclera into the connective tissue of the orbit 15 may account for 54% of outflow young healthy humans (Toris CB, Yablonski ME, Wang YL, Camras CB "Aqueous humor dynamics in the aging human eye" *Am J Ophthalmol*, 1999;127:407-12).

Cyclodialysis, the separation of the ciliary body from the scleral spur and underlying 20 sclera, creates free communication between the anterior chamber and the suprachoroidal space and enhances uveoscleral flow. It has long been known that cyclodialysis can cause a profound reduction of intraocular pressure – initially (Fuchs E. "Detachment of the choroid inadvertently during cataract surgery" [German] *von Graefes Arch Ophthalmol*, 1900;51:199-224) cyclodialysis was recognized as a complication of cataract surgery. 25 Deliberate creation of a cyclodialysis cleft for treating elevated intraocular pressure in uncontrolled glaucoma was first described as a surgical procedure in 1905 (Heine I. "Cyclodialysis, a new glaucoma operation" [German]) *Dtsch Med Wochenschr*, 1905;31:824-826. Since such clefts can heal and close spontaneously a number of devices have been used to keep them open, including platinum wire, horse hair, magnesium strips, 30 tantalum foil, supramid, gelatin film, Teflon, silicone and polymethylmethacrylate (Rosenberg LF, Krupin T. "Implants in glaucoma surgery" Chapter 88, *The Glaucomas*,

- Ritch R, Shields BM, Krupin T Eds. 2nd Edition Mosby St Louis 1986) and Hema (Mehta KR. "The suprachoroidal Hema wedge in glaucoma surgery" American Academy of Ophthalmology meeting 1977, pp 144). However the success rate of such approaches has been low (as low as 15%, Rosenburg & Krupin ibid and Gross RL, Feldman RM, Spaeth GL, et al "Surgical therapy of chronic glaucoma in aphakia and pseudophakia" *Ophthalmology*, 1988;95:1195-201). Failure was due to uncontrolled low pressure (hypotony) with consequentlal macular edema, bleeding (hyphema) and inadequate pressure control.
- 10 The device and method of a first aspect of this invention takes advantage of the methods used in cataract surgery to develop a minimally invasive glaucoma procedure – thus small, self sealing incisions and materials that are biocompatible and foldable so that they fit through small openings will reduce surgical trauma and time. The controlled draining of aqueous into the suprachoroidal space according to this invention provides some predictability of outcome and overcomes scarring problems that have plagued glaucoma implants in the past.
- 15

- The most frequent complication following modern cataract surgery with phacoemulsification, requiring specific treatment is elevated intraocular pressure (Cohen VM, Demetria H, Jordan K, Lamb RJ, Vivian AJ. :First day post-operative review following uncomplicated phacoemulsification" *Eye*, 1998;12 (Pt 4):634-6, and Dinakaran S, Desai SP, Raj PS. "Is the first post-operative day review necessary following uncomplicated phacoemulsification surgery?" *Eye*, 2000 Jun; 14 (Pt 3A):364-6. The increase may be marked and typically peaks at 5 to 7 hours before returning to near normal levels in 1 to 3 days (Hildebrand GD, Wickremasinghe SS, Tranos PG, Harris ML, Little BC. "Efficacy of anterior chamber decompression in controlling early intraocular pressure spikes after uneventful phacoemulsification" *J Cataract Refract Surg.*, 2003; 29:1087-92). Such pressure spikes can cause pain and may increase the risk of sight-threatening complications such as retinal vascular occlusion, increases loss of visual filed in advanced glaucoma and ischemic optic neuropathy – effects in otherwise healthy eyes are unknown (Hildebrand GD et al, ibid).
- 20
- 25
- 30

- A number of prophylactic treatments are used with limited success – these include intacameral carbachol or acetylcholine, topical timolol, dorzolamide, aprocyclidine, latanoprost and systemic acetazolamide (see Hildebrand GD *et al*, ibid). This also exposes
- 5 the patient to the risk of drug side effects, increased cost and it has been postulated that reducing the flow of aqueous humor post surgery prolongs the residence time of bacteria that frequently (46.3% of cases) contaminate the anterior chamber during surgery (Srinivasan R, Tiroumal S, Kanungo R, Natarajan MK. "Microbial contamination of the anterior chamber during phacoemulsification" *J Cataract Refract Surg*, 2002; 28:2173-6.).
- 10 This may increase the risk of endophthalmitis one of the most devastating sequelae of intraocular surgery, since the bacteria are not being "flushed out" of the eye by the normal production of aqueous humour, the secretion of which has been suppressed by the drugs.
- 15 Another technique is to decompress the anterior chamber by applying pressure to the posterior lip of the paracentesis wound at the appropriate time. This requires surveillance and could increase the risk of infection. Another aspect of this invention hereinafter described overcomes these problems.

Summary of the Invention

According to the present invention there is provided a flexible ocular device for

20 implantation into the eye formed of a biocompatible elastomeric material, foldable to a diameter of 1.5 mm or less, comprising a fluid drainage tube having at one end a foldable plate adapted to locate the device on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis, said drainage tube opening onto the disc at one end and opening to the anterior chamber when implanted into the eye at its other end, so as to

25 provide aqueous pressure regulation.

Preferably the fluid drainage tube has a diameter selected to provide predetermined resistance to aqueous humor flow, for example a pressure of 10 mm Hg or less. Alternatively said tube contains a valve so as to regulate pressure of the aqueous chamber

30 at a predetermined level, for example at no less than 10 mm Hg.

- 6 -

In accordance with another embodiment of this invention there is provided a method for treating glaucoma which comprises:

- providing a flexible ocular device formed of a biocompatible elastomeric material foldable to a diameter of 1.5 mm or less, comprising a fluid drainage tube having at one
5 end a foldable plate adapted to locate the device on the inner surface of the sclera and at its other end being open so as to allow fluid communication through said tube;
- forming a small self-sealing incision at the juncture of the cornea and sclera of the eye opening into the anterior chamber;
- filling the anterior chamber with a viscoelastic substance;
- 10 introducing the foldable ocular device into a suprachoroidal space formed by cyclodialysis via a hollow cannula, wherein said plate locates the device on the inner surface of the sclera in the suprachoroidal space, and said drainage tube is located in the anterior chamber of the eye so as to provide aqueous humor pressure regulation; and
- thereafter removing said cannula and viscoelastic material from the eye.
- 15

- In another aspect there is provided an ocular pressure spike shunt for insertion into an ocular paracentesis incision port following ocular surgery, comprising a flexible fluid transfer tube formed of biocompatible material, preferably biocompatible elastomeric material, so as to allow paracentesis incision closure around said tube, having an inner end
20 and an outer end, a tubular lumen disposed between said inner end and said outer end to allow fluid communication through said tube, said lumen containing a valve for controlling pressure in the eye following ocular surgery, which valve opens permitting fluid flow through said tube when a predetermined pressure is exceeded, said shunt being configured such that on insertion into a paracentesis port said outer end is substantially flush with the
25 surface of the cornea, and said inner end opens into the anterior chamber of the eye.

- In another aspect there is provided a method for preventing ocular pressure spikes following ocular surgery wherein a paracentesis incision port is formed in the eye during said surgery, comprising introducing an ocular pressure spike shunt into said paracentesis
30 port at the conclusion of ocular surgery, said shunt comprising a flexible fluid transfer tube formed of biocompatible material, preferably biocompatible elastomeric material, so as to

allow paracentesis incision closure around said tube, having an inner end and an outer end, a tubular lumen disposed between said inner end and said outer end to allow fluid communication through said tube, said lumen containing a valve for controlling pressure in the eye following ocular surgery, which valve opens permitting fluid flow through said tube when a predetermined pressure is exceeded, said shunt being configured such that on insertion into a paracentesis port said outer end is substantially flush with the surface of the cornea, and said inner end protrudes into the anterior chamber of the eye.

Description of the Figures

10 Figure 1 shows a diagrammatic representation of a side sectional view of suprachoroidal shunt insertion using an injector.

15 Figure 2 shows a diagrammatic representation of a side sectional view of an eye showing the unfolded plate portion of the device and a cannula introducing said device across the anterior chamber at 180° to the site of insertion.

Figure 3 shows a diagrammatic representation of an eye containing a pressure spike shunt inserted into a paracentesis port.

20 **Detailed Description of the Preferred Embodiments of the Invention**

The ocular device according to the present invention is implanted in a patient's eye using minimally invasive surgery techniques, adopted from modern cataract surgery.

25 The ocular device is formed from a biocompatible elastomeric material. Preferably, the device is made of soft surgical grade polymeric material, such as silicon or acrylic material such that the device is foldable and may be rolled up for insertion via a cannula. Figure 1 shows a proximal end of a cannula forming a cyclodialysis. The folded device may be introduced via such a cannula. The elastomeric material is selected to be sufficiently soft that it does not erode delicate underlying choroid material when inserted into the eye.

30 Such material and ocular lenses formed therefrom are well known and used in cataract surgery.

Sutures are not required to hold the device in place once surgically introduced into the eye, as the foldable plate is adapted to locate the device on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis (Figure 2). Preferably, the plate is of a disc-like shape which matches the curvature of the eye once unfolded. Figure 2 depicts an unfolded disc (connected tube not shown) after cannula introduction across the anterior chamber (transcameral). Alternatively, any plate-like configuration which locates the device on the inner surface of the sclera in the suprachoroidal space may be used, such as for example a rectangular foldable plate. Preferably the plate diameter is from 0.05 to 6 mm, and preferably the plate thickness is from 12.5 μ to 250 μ . The fluid drainage tube of the ocular device is preferably integral with the plate, and is attached at one end to the plate, preferably at the periphery of the plate. Alternatively, the tube may be microwelded or otherwise fixed to the plate. Fabrication techniques well known in production of intraocular foldable lenses are preferably used in this invention. The tube has a hollow lumen, and is preferably of a length from about 1 mm to 4 mm. Preferred diameters of the tubing comprise an outer diameter of 400-1000 μ , and preferably the inner diameter is from 50 to 500 μ .

The diameter of the tube may be selected so as to provide a resistance to aqueous humor flow of predetermined pressure, preferably being a pressure less than 10 mm Hg. This enables the pressure of the aqueous to be regulated in a controlled manner, providing relief from excess ocular pressure associated with glaucoma, with avoidance of hypotony (uncontrolled low pressure). Alternatively, the tube may contain a valve, for example disposed at the end of the tube opening onto the disc so as to regulate ocular pressure at a predetermined level. Preferably, the valve prevents aqueous flow through the tube at a pressure of less than 10 mm Hg. Examples of valves which may be used include a slit valve. The drainage stops altogether if the pressure drops to a predetermined threshold level controlled by the valve.

30 The flexible foldable nature of the device according to the present invention enables well established techniques used in cataract surgery to be employed in the treatment of

glaucoma. The device according to the present invention may be folded into a cannula and introduced for location into the eye.

- Intraocular surgery techniques allow a paracentesis (opening onto the anterior chamber from without at the juncture of the cornea and sclera – the limbus) to be performed and the anterior chamber filled with viscoelastic substance. A cyclodialysis instrument is introduced via the paracentesis, with the paracentesis preferably being carried out 180° from the insertion site. A cyclodialysis is carried out, for example by advancing an instrument tip into the angle between the ciliary body and sclera so as to create a cyclodialysis. This is preferably carried out with direct visualisation via gonioscopy lens viewed through an operating microscope. A surgical gonioscopy lens is preferably placed on the cornea while the cyclodialysis is carried out.

- The rolled up ocular device is introduced through a cannula, for example using an introducer such as used in cataract surgery or other ocular surgery, from which the device can be detached by pressing a plunger into the introducer when the device has been inserted into the suprachoroidal space created by the cyclodialysis. The tubing of the device is positioned into the interior chamber, and the plate unfolds in the suprachoroidal space to locate the device in the eye. Because of its size, the device cannot fall through the opening through which it was introduced into the suprachoroidal space by the cyclodialysis. The plate therefore keeps the tube in the appropriate position in the anterior chamber allowing controlled aqueous drainage and providing an effective treatment for elevated ocular pressure.

- The pressure spike shunt is designed to fit snugly in a paracentesis port that is routinely made during cataract or other ocular surgery. The tubing will not distort the port and there will be no leakage around the port. The outer end of the tube will sit flush on the surface of the cornea – the inner aspect of the tube will preferably just protrude into the anterior chamber – tube length will generally be 1-2 mm and tube diameter is preferably from 0.4-1.2 mm. The tube will contain the same valvular device as contained in the ocular device described above and will open when the intraocular pressure exceeds a predetermined

- 10 -

level, preferably 10 mm Hg. At normal ocular pressure the valve will be closed, closing said tube to any fluid communication. Figure 3 shows a shunt located in a paracentesis port. In most cases the shunt will be removed and discarded at the first post-operative dressing.

5

The shunt may be inserted into a paracentesis port, or one or more ports, using, for example, a punctum plug inserting instrument such as described in US Patent NO. 5,741,292.

10 This invention will now be described with reference to the following examples.

Example 1

Fresh whole porcine eyes were taken and mounted in a temperature controlled (37°) perfusion chamber. The eyes were perfused with Balanced Salt Solution via a 30 gauge 15 needle inserted via a paracentesis into the anterior chamber. A peristaltic pump was used at a flow rate of 2 µl/min. Intraocular pressure was continuously monitored via a second paracentesis.

20 Typically intraocular pressures stabilized at 10-15 mm Hg and fell with time (the "washout effect", as glycosan aminoglycans are washed out of the trabecular meshwork with time). Creation of a cyclodialysis (initially with a small spatula, then viscoelastic injection to enlarge the area of detachment of the ciliary body from the sclera) with or without 25 insertion of the device in the cyclodialysis cleft (silicone tubing, length 3mm, external diameter – 1 mm, plate diameter 3 mm) resulted in lower intraocular pressures (below 10 mm Hg) on reperfusion at the same perfusion rate as control eyes.

Example 2

Adequate anesthesia is provided to the eye of a glaucoma patient prepared for intraocular surgery. A paracentesis (opening into anterior chamber from without at the junction of the 30 cornea and sclera – the limbus) is performed and the anterior chamber is filled with a viscoelastic substance. A surgical goniscopy lens is placed on the cornea (or anterior

- segment endoscope is used) and a cyclodialysis instrument is introduced via the paracentesis – the paracentesis is carried out 180° away from the planned implant insertion site. The cyclodialysis instrument tip is advanced into the angle and pushed into the space between the ciliary body and sclera creating a cycodialysis – this is carried out with direct 5 visualization via the gonioscopy lens viewed through an operating microscope. In order to minimize bleeding, the area in the angle (anterior ciliary body face and overlying trabecular meshwork) can be lasered either preoperatively or at the time of surgery to ablate surface blood vessels).
- 10 Through an opening at the tip of the cyclodialysis instrument viscoelastic is inserted to further create a space in the suprachoroidal space. The implant is then introduced – the device is rolled up in the same manner as an ultrathin intraocular lens. The ocular device is attached to an introducer from which it is detached by pushing a plunger in the introducer when the implant is inserted into the suprachoroidal space created by the 15 cyclodialysis instrument and viscoelastic. The tubing is then positioned into the anterior chamber and may be cut to size. The plate unfolds in the suprachoroidal space and because of its size cannot fall through the opening through which it was introduced into the suprachoroidal space. The plate therefore keeps the tube in an appropriate position. The valve is then flushed (with a cannula inserted via the paracentesis) via the tube 20 opening in the anterior chamber. Viscoelastic is then removed from the anterior chamber and antibiotics, steroids and a dressing applied to the eye.

Example 3

- Fresh whole porcine eyes were taken and mounted in a temperature controlled (37°) 25 perfusion chamber as in Example 1. The eyes were perfused with Balanced Salt Solution via a 30 gauge needle inserted via a paracentesis into the anterior chamber. A peristaltic pump was used at a flow rate of 2 µl/min. Intraocular pressure was continuously monitored via a second paracentesis.

- 30 Typically intraocular pressures stabilized at 10-15 mmHg and fell with time (the "washout effect, as glycoaminoglycans are washed out of the trabecular meshwork with

- 12 -

time). Silicone tubing, length 3 mm, external diameter 1 mm was introduced into one paracentesis port. One end of the port (outer end) was flush with the cornea and the inner end of the port extended slightly into the anterior chamber. Intraocular pressure did not exceed 10 mm Hg.

Claims

1. A flexible ocular device for implantation into the eye formed of a biocompatible elastomeric material, foldable to a diameter of 1.5 mm or less, comprising a fluid drainage tube having at one end a foldable plate adapted to locate the device on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis, said drainage tube opening onto the disc at one end and opening to the anterior chamber when implanted into the eye at its other end, so as to provide aqueous pressure regulation.
10
2. A device according to claim 1 wherein said fluid drainage tube has a diameter selected to provide predetermined resistance to aqueous flow.
3. A device according to claim 2 wherein said predetermined resistance is at a pressure of 10 mm Hg or less.
15
4. A device according to claim 1 wherein said tube contains a valve so as to regulate pressure of the aqueous at a predetermined level.
20
5. A device according to claim 4 wherein said predetermined level is a pressure of 10 mm Hg or less.
6. A device according to claim 1 wherein said plate has a diameter from 0.05 to 6 mm and a thickness from 12.5 μ to 250 μ .
25
7. A device according to claim 1 wherein said tube has a length from 1 mm to 4 mm.
8. A device according to claim 1 wherein said tube comprises an outer diameter of 400-1000 μ and an inner diameter from 50 to 500 μ .
30
9. A device according to claim 4 wherein said valve comprises a slit valve.

10. A method for treating glaucoma which comprises:

5 providing a flexible ocular device formed of a biocompatible elastomeric material foldable to a diameter of 1.5 mm or less, comprising a fluid drainage tube having at one end a foldable plate adapted to locate the device on the inner surface of the sclera and at its other end being open so as to allow fluid communication through said tube;

10 forming a small self-sealing incision at the juncture of the cornea and sclera of the eye opening into the anterior chamber;

15 filling the anterior chamber with a viscoelastic substance;

introducing the foldable ocular device into a suprachoroidal space formed by cyclodialysis via a hollow cannula, wherein said plate locates the device on the inner surface of the sclera in the suprachoroidal space, and said drainage tube is located in the anterior chamber of the eye so as to provide aqueous humor pressure regulation; and

15 thereafter removing said cannula and viscoelastic material from the eye.

20 11. A method according to claim 10 wherein said fluid drainage tube has a diameter selected to provide predetermined resistance to aqueous flow.

25 12. A method according to claim 10 wherein wherein said predetermined resistance is at a pressure of 10 mm Hg or less.

13. A method according to claim 10 wherein said tube contains a valve so as to regulate 25 pressure of the aqueous at a predetermined level.

14. A method according to claim 13 wherein said predetermined level is a pressure of 10 mm Hg or less.

30 15. A device according to claim 10 wherein said plate has a diameter from 0.05 to 6 mm and a thickness from 12.5 μ to 250 μ .

- 15 -

16. A method according to claim 10 wherein said tube has a length from 1 mm to 4 mm.
- 5 17. A method according to claim 10 wherein said tube comprises an outer diameter of 400-1000 μ and an inner diameter from 50 to 500 μ .
18. A method according to claim 13 wherein said valve comprises a slit valve.
- 10 19. An ocular pressure spike shunt for insertion into an ocular paracentesis incision port following ocular surgery, comprising a flexible fluid transfer tube formed of biocompatible material, preferably biocompatible elastomeric material, so as to allow paracentesis incision closure around said tube, having an inner end and an outer end, a tubular lumen disposed between said inner end and said outer end to allow fluid communication through said tube, said lumen containing a valve for controlling pressure in the eye following ocular surgery, which valve opens permitting fluid flow through said tube when a predetermined pressure is exceeded, said shunt being configured such that on insertion into a paracentesis port said outer end is substantially flush with the surface of the cornea, and said inner end opens into the anterior chamber of the eye.
- 15 20. A shunt according to claim 19 wherein said predetermined pressure is 10 mm Hg.
20. A method for preventing ocular pressure spikes following ocular surgery wherein a paracentesis incision port is formed in the eye during said surgery, comprising introducing an ocular pressure spike shunt into said paracentesis port at the conclusion of ocular surgery, said shunt comprising a flexible fluid transfer tube formed of biocompatible material, preferably biocompatible elastomeric material, so as to allow paracentesis incision closure around said tube, having an inner end and an outer end, a tubular lumen disposed between said inner end and said outer end to allow fluid communication through said tube, said lumen containing a valve

- 16 -

for controlling pressure in the eye following ocular surgery, which valve opens permitting fluid flow through said tube when a predetermined pressure is exceeded, said shunt being configured such that on insertion into a paracentesis port said outer end is substantially flush with the surface of the cornea, and said inner end extends
5 into the anterior chamber of the eye.

FIGURE 1

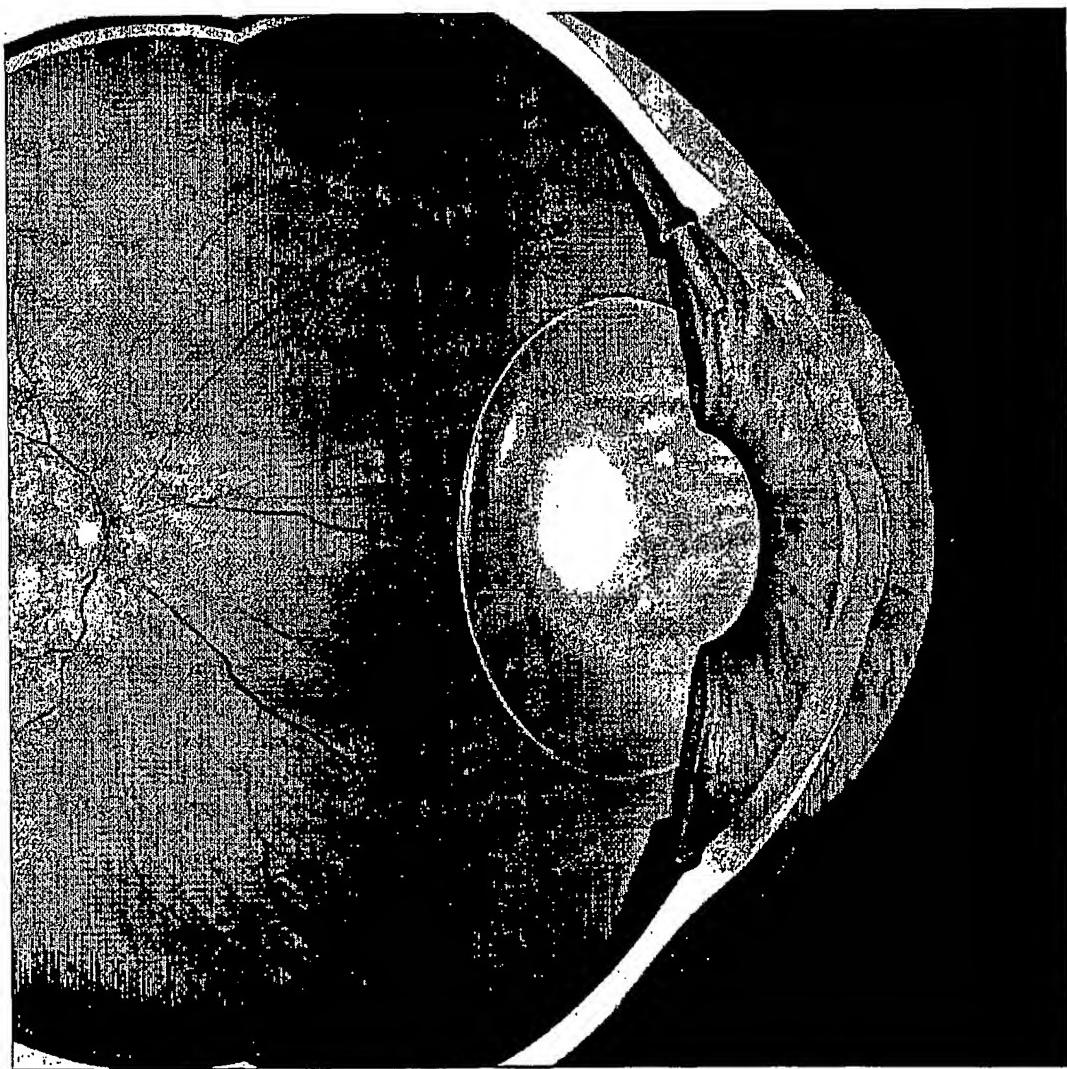


FIGURE 2

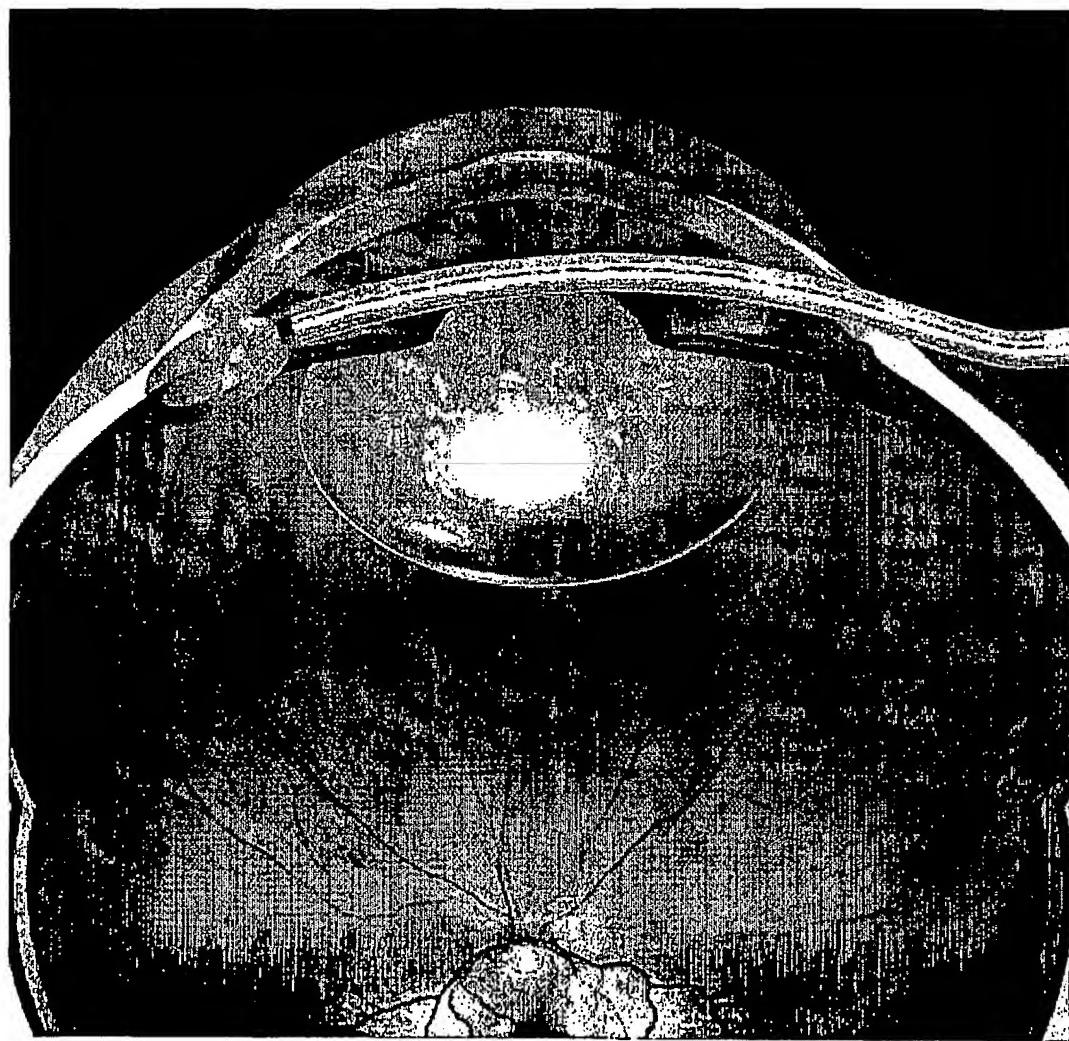
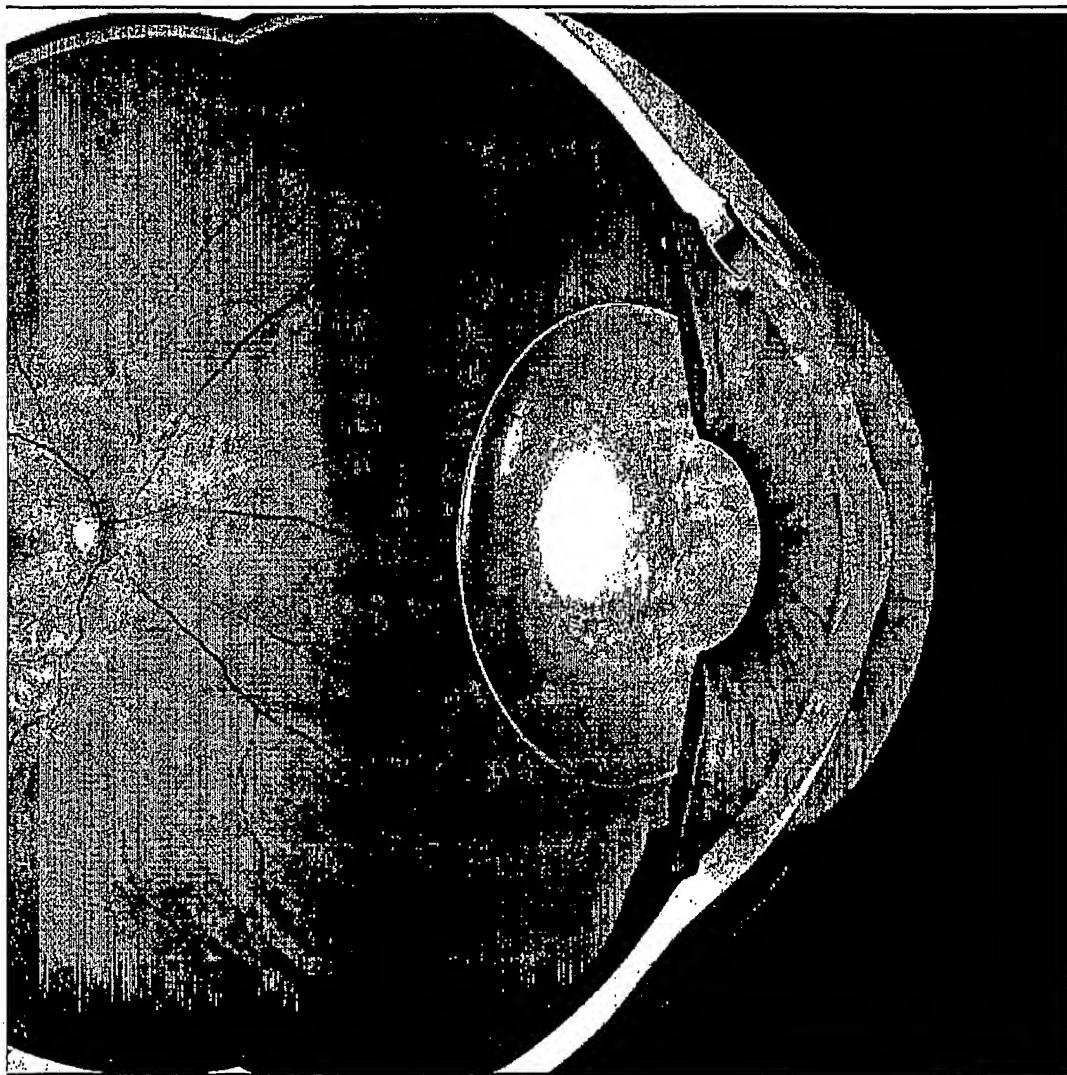


FIGURE 3



INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001566

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61M 27/00, A61F 9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI IPC A61M, A61F, A61B & keywords: eye, tube, plate, fold, valve and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,788,327 A (DONOWITZ et al) 29 January 1974 Figures 1 and 4, column 2 lines 21 to 28 and column 2 line 65 to column 3 line 2	19,21
Y		20
Y	US 5,743,868 A (BROWN et al) 28 April 1998 Column 6 lines 40 to 42	20
A	US 6,186,974 B1 (ALLAN et al) 13 February 2001 Column 7 lines 56 to 58 and column 17 lines 39 to 56	
A	US 6,471,666 B1 (ODRICH) 29 October 2002 Abstract	

 Further documents are listed in the continuation of Box C See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
13 January 2005

Date of mailing of the international search report

17 JAN 2005

Name and mailing address of the ISA/AU

Authorized officer

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

XAVIER GISZ

Telephone No : (02) 6283 2064

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001566

C (Continuation). - DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,468,283 B1 (RICHTER et al) 22 October 2002 Abstract	
A	US 6,595,945 B2 (BROWN) 22 July 2003 Abstract	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001566

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

First invention Claims 1-18

Second invention Claims 19-21

See extra sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid; specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001566

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III.

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-18 are directed to a flexible ocular device comprising a foldable plate attached to the end of a tube wherein the foldable plate is located in the suprachoroidal space and the other end of tube opening to the anterior chamber. It is considered that a foldable plate located in the suprachoroidal space in fluid communication with the anterior chamber comprises a first "special technical feature".
2. Claims 19-21 are directed to an ocular pressure spike shunt comprising a flexible transfer tube extending from the anterior chamber to the surface of the cornea. It is considered that a flexible fluid transfer tube extending from the anterior chamber to the surface of the cornea comprises a second special technical feature.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, *a priori*.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU2004/001566

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	3788327						
US	5743868						
US	6186974	AU	55666/98	AU	55676/98	EP	0953001
		EP	0977531	US	6673883	WO	9830181
		WO	9830615	ZA	9800174		
US	6471666	US	2002193725				
US	6468283	AU	58573/96	CA	2220355	CN	1189780
		CN	1449841	EP	0957949	EP	1473004
		HK	1015290	IL	113723	US	5702414
		US	5868697	US	5968058	US	2002177856
		US	2004088048	WO	9636377		
US	6595945	CA	2433849	US	2002169468	US	2004073156
		WO	02070045				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX